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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,497	07/24/2006	Yasuhiko Tabata	17195/006001	4614

22511 7590 10/19/2007

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EXAMINER	
STOICA, ELLY GERALD	

ART UNIT	PAPER NUMBER
1647	

NOTIFICATION DATE	DELIVERY MODE
10/19/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/551,497	TABATA ET AL.	
	Examiner	Art Unit	
	Elly-Gerald Stoica	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

1. The Applicant's note regarding the pending claims in the amendment filed on 07/30/2007 is acknowledged by the Examiner. Inadvertently another version of the claims, containing only claims 1-5 was considered for the Office action of 04/30/2007. Accordingly the claims pending are 1-10 as presented in the amended set of 07/30/2007.

Claim Rejections - 35 USC § 112

2. Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Specifically, the amended independent claim 1 now recites that the gradually release of HGF is continued for about 4 weeks. Contrary to the assertion of the Applicant that the amendment does not introduce new matter, citing as evidence paragraphs [0065] of the Application, the evidence is against this assertion. Thus the cited paragraph states:

"Direct administration of HGF gradual release agent to heart muscle resulted in a remarkable improvement of coronary contraction and coronary systole for 4 weeks after surgery. This technique was suggested to not only inhibit progression of dilation cardiomyopathy, but also demonstrate aggressive therapeutic effects" ([0065]).

However, in designing the experiment Applicant discloses that:

"An HGF gradual release agent was prepared according to the method of Tabata et al. so that the gradual release of HGF continued for about 4 hours after administration. A dilated cardiomyopathy model was prepared by inducing acute myocarditis by subcutaneously administering myosin derived from porcine heart muscle to Lewis rats (males, n =9, purchased from Shimizu Laboratory Animals) followed by allowing six weeks to elapse to induce cardiomyopathy. These animals were divided into an HGF treatment group (n =4) and a sham group (n=5). A gelatin sheet immersed with HGF gradual release agent was affixed to the left ventricular anterior wall of the animals of the HGF treatment group following thoracotomy to promote subsequent gradual release of HGF, while a gelatin sheet immersed with saline was adhered to the left ventricular anterior wall of the animals of the sham group. The size and function of the heart were followed up for 4 weeks after surgery by echocardiography using an ultrasonic probe at a frequency of 10 to 12 MHz " [0057].

Thus the specification clearly states that the preparation was designed for gradual release for about four hours and not for weeks.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite for failing to point out the conditions of gradual release of the HGF for about four weeks.

Claims 3-10 are indefinite because, since they are drawn to a composition, it is unclear how the intended use would alter the composition.

Therefore, the claims being indefinite, the meets and bounds of the claims could not be established.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. Claims 1-10 are rejected under 35 U.S.C. 102(a) as being anticipated by Tambara et al. (Circulation, 106, supplement, p II-350, Nov., 2002, Meeting abstract)).

The claims are drawn to a cardiomyopathy therapeutic agent that contains hepatocyte growth factor (HGF) and gelatin hydrogel, and gradually releases HGF.

Tambara et al. teach a controlled release of HGF via gelatin hydrogel sheets that, in a rat model of dilated cardiomyopathy, improves left ventricular function. Since the Office does not have laboratory facilities to check if the gel used in the experiment has the same properties as the gelatin described in claim 2, it is considered that the properties of the gelatin of Tambara et al. are the same to the gelatin claimed. This assumption is strengthened by the fact that the Applicants are part of the co-authors of the prior art communication. Since the Office does not have the facilities for examining

and comparing applicants' protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

Regarding intended use of a composition, the Office gives patentable weight only insofar as it affects the agent per se. Since the composition is the same, the intended use, be it dilation cardiomyopathy, hypertrophic cardiomyopathy, idiopathic cardiomyopathy, primary cardiomyopathy or secondary cardiomyopathy does not constitute patentable subject matter and is considered anticipated by the prior art reference.

Prior art made of record

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure is: Nakamura et al. (U.S. Pat. No.: 6,036,972) and Komeda et al. (U.S. Pat. No.: 6,732,738). The prior art is relevant because:

- Komeda et al. teach a method of treatment that uses a biodegradable hydrogel comprising acidic gelatin to enable HGF to be released at the site of action for extended time period.
- Nakamura et al. teach a method of treating a patient with dilated cardiomyopathy comprising administering an effective amount of HGF.

Double Patenting

9. The double patenting rejection made in the previous office action is withdrawn in view of the Terminal disclaimer filed by Applicant on 07/30/2007.

Conclusion

10. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elly-Gerald Stoica whose telephone number is (571) 272-9941. The examiner can normally be reached on 8:30-17:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER